

BC WOMEN'S SEXUAL ASSAULT SERVICE

DECISION SUPPORT TOOL FOR RN SANES DISPENSING HIV POST- EXPOSURE PROPHYLAXIS (PEP) AFTER SEXUAL ASSAULT

PURPOSE

This decision support tool (DST) and accompanying documents have been developed to assist Registered Nurses (RNs) working in hospital emergency departments as sexual assault nurse examiners (SANEs) to assess the sexual assault patient's risk of exposure to HIV, and safely offer and dispense a five-day supply of HIV post-exposure prophylaxis (PEP) when appropriate. RNs using this DST must meet The "*Competencies for RN SANEs Dispensing Prophylactic Medications to Protect Against STI and HIV After Sexual Assault*," established by BC Women's Sexual Assault Service (BCW SAS).

RN SANEs will refer to the emergency physician for patient-specific medication orders when the patient is pregnant or breastfeeding.

See, Decision Support Tool For RN SANES Dispensing Prophylaxis For Sexually Transmitted Infection After Sexual Assault, for risk assessment and prophylaxis for chlamydia, gonorrhea, and hepatitis.

To be sure you have the most recent version of this DST please contact BCW SAS at 604-875-3284 or visit our website bcwomens/sas under resources



BC WOMEN'S SEXUAL ASSAULT SERVICE (SAS) Guidelines for Offering HIV Post Exposure Prophylaxis (PEP) Following a Sexual Assault RISK ASSESSMENT GUIDE

Significant Risk: May be indicated by what is known about the <u>source</u> **or** what is known about the <u>setting</u> in which the sexual assault took place.

SOURCE <u>Known</u> HIV positive source or <u>Known</u> high-risk source [e.g., injection drug user (IDU) or man who has sexual contact with men (MSM)] or <u>Known</u> multiple assailants	PLUS	TYPE OF EXPOSURE Non-consensual: Unknown exposure or Anal penetration or Vaginal penetration	RECOMMENDATIONS Recommend five-day HIV PEP starter kit initiated within 72 hours of sexual assault, AND baseline HIV bloodwork drawn
SETTING Sexual assault occurs in a setting considered high risk for HIV (e.g., Vancouver's Downtown Eastside, drug paraphernalia at scene, etc)	PLUS	TYPE OF EXPOSURE Non-consensual: Unknown exposure or Anal penetration or Vaginal penetration	RECOMMENDATIONS Recommend five-day HIV PEP starter kit initiated within 72 hours of sexual assault, AND baseline HIV bloodwork drawn See Important Notes below.

Negligible Risk:

Vaginal/anal penetration occurred but the source is known to be HIV negative (or there is no reason to believe the source is HIV positive or in a high risk group (IDU or MSM)) AND the setting in which the assault took place is not considered high risk for HIV. Oral exposure alone is considered to be negligible risk regardless of HIV status of source.	RECOMMENDATION Do not offer PEP to patients in this category. Provide counselling and education to reduce anxiety. Recommend HIV testing at one and three months post sexual assault
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Important Notes Regarding Initiating PEP:

- If the patient is currently on any medication, contact the St. Paul's Hospital Outpatient Pharmacy at 1-888-511-6222 to check for possible interactions between current medications and HIV PEP.
- HIV PEP is not offered after 72 hours from a possible exposure and is most effective if initiated within 2 hours of exposure. Delays should be avoided. If a patient meets the criteria for significant risk and PEP is indicated, but patient is unsure about taking PEP, suggest that the patient begin the starter kit immediately and review the decision later, rather than delay prophylaxis.
- For "multiple assailants" to be considered a significant risk factor, more than one assailant must be known to have potentially exposed the patient through vaginal penetration, anal penetration or unknown exposure.
- "Unknown exposure" refers to when the patient was unconscious at the time of the sexual assault or has no memory of the assault but other circumstances indicate a sexual assault took place.
- For patients sexually assaulted by a regular partner, where the partner is known to be HIV positive, dispense PEP if the patient is in the "significant-risk" category.

If you are uncertain about whether to initiate HIV PEP, or if the patient is taking any medications (prescription and non-prescription) consult one of the following available 24/7:

- St. Paul's Hospital Outpatient Pharmacy at 1-888-511- 6222.
- The Physician's Hotline for the BC Centre for Excellence in HIV/AIDS at 1-800-665-7677

Estimated Risks of Becoming Infected With HIV

Estimated risks in <u>consensual</u> sex from a known HIV positive source with a positive viral load: Receptive Vaginal: 0.08% (8 in 10,000) Receptive Anal Penetration: 1.38% (138 in 10,000) Receptive Oral: Low (BC Centre For Excellence in HIV/AIDS May 2017)

In <u>non- consensual</u> sex after one exposure (where one person is known to be HIV positive), the risk maybe higher than the risk in consensual sex because of potential injuries, but the numbers are unknown.

Dispensing HIV PEP

The BC Centre for Excellence in HIV/AIDS provides medications for prophylaxis of HIV after sexual assault where the risk is assessed to be significant. Five-day HIV post-exposure prophylaxis (PEP) starter kits containing tenofovir, lamivudine, and raltegravir are available in all emergency rooms, outpost nursing stations and provincial prisons in BC. The remaining 23 days of the 28-day regimen will be dispensed by St. Paul's

Hospital Outpatient Pharmacy in Vancouver in collaboration with the patient's follow-up physician or nurse practitioner.

Medication Dosage

It is recommended the patient take PEP for a total of 28 days starting as soon as possible within 72 hours of exposure. The first five days of medication is dispensed in the emergency department.

The PEP starter kit consists of a 5 day supply of:

- Tenofovir one tablet (300 mg) once a day
- Lamivudine one tablet (150 mg) twice a day
- Raltegravir one tablet (400 mg) twice a day

IF PATIENT'S WEIGHT <40 kg, call the St. Paul's Hospital Outpatient pharmacist for dosage adjustment at 1-888-511-6222.

Common Side Effects

- Tenofovir: Tenofovir is usually well tolerated and side effects are generally mild. They may include nausea, diarrhea and gas. Rarely, patients have had kidney changes when taking tenofovir and appropriate lab testing should be done. Close monitoring is advised in patients with a history of kidney disease, risk factors for kidney disease (e.g. diabetes, hypertension), or who are receiving concomitant medications with nephrotoxic potential (e.g. high dose non-steroidal anti-inflammatory drugs [NSAIDS]). Commencing the 5 day starter pack with Tenofovir is generally not an issue. (BC Centre for Excellence in HIV/AIDS, 2017).
- Lamivudine: Lamivudine is usually well tolerated in short-term therapy and side effects are rare. A reversible decrease in white blood cell count is the most common side effect but is very rare. Tingling of the hands and feet (peripheral neuropathy) is very unlikely to occur with one month of treatment.

(BC Centre for Excellence in HIV/AIDS, 2017).

 Raltegravir: Raltegravir is generally well tolerated. Side effects are uncommon and can include headache, insomnia, fatigue, dizziness, mild abdominal pain, vomiting, and diarrhea. (BC Centre for Excellence in HIV/AIDS, 2017).

A BC Centre for Excellence in HIV/AIDS physician may recommend modification of the regimen in the following situations:

- Significant toxicity or intolerance
- Source on antiretroviral therapy and/or has history of known or suspected resistance to any agents in the PEP regimen
- If the exposed person is pregnant, contact the BC-CfE pharmacy (1-888-511- 6222) for advice. However, in a significant exposure, the existing kit should be given as soon as possible. (BC Centre for Excellence in HIV/AIDS, 2017).

HIV PEP Contraindications

Medications may interact significantly with HIV PEP and should be used with caution. A careful
medication history, including prescription and non-prescription medications, supplements and
alternative therapy) should be obtained if the patient is on any medication (prescription or nonprescription) contact the St. Paul's Hospital Outpatient pharmacist at 1-888-511-6222 or
The Physician's Hotline for the BC Centre for Excellence in HIV/AIDS at 1-800-665-7677

Avoid or use with extreme caution in persons with chronic renal insufficiency (estimated glomerular filtration rate [eGFR] <50 mL/min. Specific cases should be discussed with a BC-CfE physician or pharmacist.

(BC Centre for Excellence in HIV/AIDS, 2017).

HIV Testing Prior To PEP Adminstration

- With patient consent, an HIV Ag/Ab baseline blood test, CBC and differential, creatinine and eGFR should be done on all patients who are going to be dispensed PEP.
- Inform patients that the HIV test is checking their HIV status from before the assault and not assessing potential HIV from the assault itself. Inform the patient that you are doing the test to ensure it is safe for them to take PEP.
- As with all of care, patients can decline a HIV test. If that should happen, be sure to document that on the patient's hospital chart.

Specific To Women's Health

- Tenofovir,— lamivudine, and raltegravir are recommended antiretroviral agents both for treatment of HIV during pregnancy and for PEP in pregnant women. (BC-CfE PEP Guidelines May 2017)
- Tenofovir is a Pregnancy Category B drug. When pregnancy is confirmed or suspected, consultation with St. Paul's Outpatient Pharmacy at 1-888-511-6222 and BC Women's Hospital Oak Tree Clinic at 604-875-2212 is highly recommended. On weekends or after office hours, the patient may begin the regular five-day PEP starter kit and contact the Oak Tree Clinic at 604-875-2212 the next business day.
- Breastfeeding should be discontinued if suspicion of HIV infection is high enough to initiate PEP. An infant born to an HIV positive mother has a 14% higher chance of HIV infection if she is breastfed by her mother (Dunn, Newell, Ades, and Peckham, 1992). Additionally, the PEP medication can pass into the breast milk causing side effects for the infant. For these reasons it is strongly recommended that the patient discontinues breastfeeding immediately and switch to using infant formula (and pumping and discarding her breast milk). Possible resumption of breast- feeding can be discussed in follow-up if HIV risk is reassessed as insignificant or repeat HIV tests are negative. BC Women's Hospital Oak Tree Clinic at 604-875-2212 is available for consultation for breastfeeding mothers taking PEP.

Patient Teaching

- Give the starter kit. Review and be sure the patient understands how to take the medication and is aware of the possible side effects.
- Review and ensure patient understands the education handouts titled, *Taking HIV Post Exposure Prophylaxis? What To Do After You Leave Emergency* and *Take This To Your Doctor. These patient handouts are available on the BC Women's Hospital Sexual Assault Service website under resources.*
- Discuss protecting others from possible exposure. Consider the following recommendations until patient receives a negative HIV test result 3 months after possible exposure.
 - Abstain from vaginal and anal intercourse or use a latex condom with a water-based lubricant.
 - o Do not donate blood, plasma, organs, tissue or sperm
 - Do not become pregnant
 - Do not share toothbrushes, razors, needles or other items which may be contaminated with blood/body fluids.
 - Do not breastfeed

The risk of transmission to others is extremely small and the need for precautions should be discussed with a consultant familiar with HIV transmission.

• Inform the patient that the St. Paul's Hospital Outpatient Pharmacy in Vancouver is closed on weekends and holidays. To prevent any disruption in treatment, recommend the patient sees a doctor within the first two days of initiating PEP to obtain a prescription for the remaining 23 days of medication, and to arrange for pickup or delivery.

Follow Up HIV Testing

The BC Centre for Excellence in HIV/AIDS (May 2017) recommends patients have the following bloodwork done while taking PEP and after completing it:

- Weeks 2 and 4 weeks after exposure (while on PEP): CBC and differential, creatinine, eGFR. If abnormalities were present on baseline testing.
- Weeks 3 and 6 weeks after end of PEP: HIV Ag/Ab test
- 3 months after end of PEP: HIV Ag/Ab test

Please Note

The cost for PEP medications for sexual assault patients who are from a province other than BC or from outside of Canada are covered by BC Centre for Excellence in HIV/AIDS. The follow-up physician may have to remind the St. Paul's Hospital Outpatient Pharmacy (at 1-888-511-6222) that out-of-province /country sexual assault patients are covered.

DEFINITIONS & ABBREVIATIONS

Antiretroviral - describes medications for the treatment of infection by retroviruses, primarily HIV

BCW SAS - BC Women's Sexual Assault Service, part of Children's and Women's Health Centre of British Columbia Branch, an agency of the PHSA

Consult – seeking assistance of other health care providers in making clinical judgements

Decision Support Tool (DST) – evidence-based document used by RNs to guide assessment, diagnosis and treatment of client-specific clinical problems. RNs may use DSTs to direct their practice but they should be used in conjunction with clinical judgement, available evidence, and following discussion with professional colleagues.

Dispensing – the preparation and transfer of a medication to a client, taking steps to ensure its pharmaceutical and therapeutic suitability and its proper use. (CRNBC, 2010)

Hepatotoxic - having a damaging effect on the liver. A side effect of many medications

Immunoprophylactic - vaccination to prevent disease

IDU – injection drug user

MSM - men who have sexual contact with men

Multiple assailants – more than one person must have potentially exposed the patient through vaginal-penile, anal-penile, or unknown exposure, for the patient to be considered at significant risk due to multiple assailants

Nephrotoxic - having a damaging effect on kidney tissue. A side effect of a number of classes of medication

PEP - post-exposure prophylaxis

Peripheral neuropathy - damage to the peripheral nervous system causing numbness, burning, tingling and sometimes severe pain in the toes, feet, legs, hands and/or arms

Prophylactic - an agent used to prevent disease

Prophylaxis - measures taken to prevent disease; common term for chemo-prophylaxis

SANE - sexual assault nurse examiner

Seroconversion - the development of antibodies to a particular antigen (infectious organism); in this case, HIV

Sexual assault - any form of sexual activity with another person without that person's consent

Sexual assault nurse examiner - RN with training in comprehensive care for sexual assault patients. Competencies include but are not limited to; crisis support, advocacy, health assessment, medication dispensation, forensic exam, collection of forensic samples and documentation of injuries.

REFERENCES

Abbott Laboratories, Limited. (2010). *Product Monograph Kaletra* ® Saint-Laurent (QC). Submission Control No:1133239

 $http://www.abbott.ca/static/cms_workspace/en_CA/content/document/Kaletra-PM-09AUG10.pdf$

BC Centre for Excellence in HIV/AIDS. (2017). *Guidance for The Use Of Post-Exposure Prophylaxis* (PEP) For The Prevention of HIV Acquisition In British Columbia. Vancouver (BC), 2017

CRNBC. (2010). Practice Standard for Registered Nurses and Nurse Practitioners: Dispensing Medications. <u>https://www.crnbc.ca/Standards/Lists/StandardResources/486DispensingMedications.pdf</u>

Division of HIV/AIDS Prevention, National Centre for HIV, STD, and TB Prevention, CDC, Atlanta, Georgia et al. (2005). Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States Recommendations from the U.S. Department of Health and Human Services. *MMWR*, 54(RR02) 1-20. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm

Dunn, D.T., Newell, M.L., Ades, A.E., Peckham, C.S. (1992). Risk of human immunodeficiency virus type 1 transmission through breastfeeding. *Lancet*, 340, 585-588.

ISMP Canada. (2008). Drug Interaction Incident with HIV Post-exposure Prophylaxis. *ISMP Canada Safety Bulletin*, 8(3) 1-2.